

REMARKS/ARGUMENTS

Claims 1-10 and 12 have been rejected. Claim 8 has been amended for formatting and claim 12 has been amended to remove the words “or preventing”. Accordingly, no new matter has been introduced by way of these claim amendments.

Claims 1-10 and 12 are currently pending in the application. Reexamination and reconsideration of the claims are respectfully requested in view of the following remarks. The Examiner’s comments in the Office Action dated May 27, 2008 are addressed below in the order set forth therein.

The Objection to the Claims Should Be Withdrawn

Claim 8 was objected to for informalities relating to a lack of indentations for a plurality of elements. Claim 8 has been amended to remove the table and replace it with subsections a) to f), which set forth the components of the claimed composition. Accordingly, Applicants submit that this rejection has been obviated and request that it be withdrawn.

The Rejection Under 35 U.S.C. §112, First Paragraph, Should Be Withdrawn

Claim 12 has been rejected under 35 U.S.C. §112, First Paragraph, for lack of enablement with respect to the prevention of obesity in human subjects. The Examiner concedes that the specification is enabling with respect to reducing or lowering excess body fat in human subjects. Claim 12 has been amended to remove reference to preventing obesity. Accordingly, Applicants submit that this rejection has been obviated and request that it be withdrawn.

The Rejection Under 35 U.S.C. §102(b) Should Be Withdrawn

Claims 1-2, 5-6, 9-10, and 12 have been rejected under 35 U.S.C. §102(b) as being anticipated by Halvorsen et al. (U.S. Patent App. Pub. No. 2001/0041708). Applicants traverse this rejection for the reasons provided below.

Halvorsen *et al.* disclose a composition for treating or preventing cellulite, said composition comprising conjugated linoleic acid and a pharmaceutically acceptable carrier (paragraph [0012]). The composition can comprise from about 0.1% to about 10% by weight of

10-trans, 12-cis conjugated linoleic acid (paragraph [0013]). Moreover, it is stated in paragraph [0043] that the composition can further comprise additional materials, *e.g.* xanthine derivatives such as theophylline, caffeine, theobromine or salts thereof. Paragraphs [0052] and [0053] recite that the preferred xanthine employed is caffeine and/or theophylline and that the xanthine is present in an amount of at least 0.05%, generally from 0.05 to 20%.

Claims 1 and 2 are directed to a composition comprising a combination of conjugated linoleic acid and caffeine in which the conjugated linoleic acid/caffeine mass ratio is between 1 and 15 (claim 1) or between 1 and 6 (claim 2). Claims 5-6, 9-10, and 12 all depend directly or indirectly from either claim 1 or claim 2 and incorporate the limitations of their base claims. The Examiner asserts that the conjugated linoleic acid/caffeine mass ratio disclosed by Halvorsen *et al.* is between 0.005 and 200, and that these proportions read on the ranges recited in claims 1 and 2. However, the claimed ranges of mass ratios in pending claims 1 and 2 are much narrower than in the Halvorsen *et al.* reference.

Where claims are directed to a narrow range and a reference teaches a broad range that encompasses the narrow range, the narrow range is not disclosed with “sufficient specificity” to constitute an anticipation of the claims. *Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999, 78 USPQ2d 1417, 1423 (Fed. Cir. 2006). In *Atofina* the court held that a temperature range of 100-500 °C disclosed in a reference did not describe a claimed range of 330-450 °C with sufficient specificity to be anticipatory. *Id.* In its holding, the court stated that “it is well established that the disclosure of a genus in the prior art is not necessarily a disclosure of every species that is a member of that genus.” *Id.* Although the court acknowledged that “a very small genus can be a disclosure of each species within the genus”, it held that “the temperature range of over 100 degrees is not a small genus”. *Id.*

In the present case, the claimed ranges of mass ratios (between 1 and 15 or between 1 and 6) are much narrower ranges than the claimed range in *Atofina*, and the disclosed range in the Halvorsen *et al.* reference is much broader than the prior art range at issue in *Atofina*. Applicants therefore submit that the disclosure by Halvorsen *et al.* does not describe the ranges within the present claims with sufficient specificity to constitute an anticipation of the claims. Accordingly, Applicants request that this rejection be withdrawn.

The Rejection Under 35 U.S.C. §103(a) Should Be Withdrawn

Claims 1 and 3-8 have been rejected under 35 U.S.C. §103(a) as being obvious in view of Halvorsen *et al.* in combination with Alviar *et al.* (U.S. Patent No. 6,413,545). Applicants traverse this rejection for the reasons provided below.

The teachings of Havorsen *et al.* have been described above. Alviar *et al.* disclose a diet composition for managing body weight comprising a *Garcinia cambogia* extract, a *Gymnema sylvestre* extract, chromium picolinate, vanadium compound, L-carnitine, and conjugated linoleic acid. It is stated that the composition may include other components, such as a kola nut extract as a source of caffeine, for its stimulatory and antidiuretic effects. In the only example of the document, the kola nut extract is contained in a capsule B and the conjugated linoleic acid is contained in a capsule C.

To establish *prima facie* obviousness of a claimed invention, all the claim features must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). However, neither Halvorsen *et al.* or Alviar *et al.* teach or suggest the limitation of claims 1 and 3-8 that the claimed composition comprise a combination of conjugated linoleic acid and caffeine in which the conjugated linoleic acid/caffeine mass ratio is between 1 and 15. As described above, the claimed range of mass ratios is much narrower than the range disclosed in the Halvorsen *et al.* reference. Alviar *et al.* suggest that the kola nut extract used in their composition has a minimum of 10% caffeine content (Col. 6, lines 5-8). Although the only example in Alviar *et al.* fails to describe a single composition that contains both conjugated linoleic acid and caffeine, using the amounts listed for the conjugated linoleic acid in the sunflower oil of capsule C (60% of 525 mg = 315 mg) and the caffeine in the kola nut extract of capsule B (10% of 110 mg = 11 mg), the mass ratio of conjugated linoleic acid/caffeine would be much higher than the claimed ratios ($315/11 = 28.6$). There is no teaching or suggestion in either Alviar *et al.* or Halvorsen *et al.* to modify or adjust their listed mass ratios to fall within the claimed ratio of 1 to 15. Accordingly, because neither Halvorsen *et al.* or Alviar *et al.*, alone or in combination, teach or suggest this limitation of claims 1 and 3-8, Applicants submit that the Examiner has not established a *prima facie* case of obviousness.

Although Applicants do not believe that the Examiner has established a *prima facie* case of obviousness, even if a *prima facie* case of obviousness had been established, evidence of unobvious or unexpected advantageous properties can rebut *prima facie* obviousness. *In re Chupp*, 816 F.2d 643, 646, 2 USPQ2d 1437, 1439 (Fed. Cir. 1987); *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963). The Federal Circuit has expressly stated that:

One way for a patent applicant to rebut a *prima facie* case of obviousness is to make a showing of “unexpected results,” i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the art would have found surprising or unexpected. The basic principle behind this rule is straightforward – that which would have been surprising to a person of ordinary skill in a particular art would not have been obvious.

In re Soni, 54F.3d 746, 34 USPQ2d 1684, 1687 (Fed Cir. 1995).

The experimental results provided within the present application clearly demonstrate an unexpected synergistic result for the claimed composition. As described on pages 5-6 of the English language translation of the International Application, the administration of caffeine alone or conjugated linoleic acid alone did not result in a significant amount of weight loss among subjects. However, when caffeine and conjugated linoleic acid were combined in the same formulation, this combination resulted in a significant amount of weight loss among subjects and confirmed “the synergy between caffeine and conjugated linoleic acid on weight loss” (see page 6). Applicants submit that this evidence demonstrating unexpected advantageous results (i.e., a positive synergistic effect) for the claimed composition is sufficient to overcome any *prima facie* case of obviousness. Accordingly, Applicants request that this rejection be withdrawn.

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CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the objection to the claims and rejections under 35 U.S.C. §§ 112, First Paragraph, 102(b), and 103(a) are overcome. Accordingly, Applicants submit that this application is now in condition for allowance. Early notice to this effect is solicited.

It is not believed that extensions of time or fees for net addition of claims are required. However, in the event that extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 C.F.R. §1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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